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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,157	10/30/2001	Jian Chen	P1381R1C1P4	8259

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GENENTECH, INC.

1 DNA WAY

SOUTH SAN FRANCISCO, CA 94080

EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

14

DATE MAILED: 01/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/000,157

Applicant(s)

CHEN ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9, drawn to an isolated nucleic acid, a vector containing same, a host cell thereof, and a method of recombinantly producing the encoded polypeptide, classified in class 435, subclass 69.5.
 - II. Claims 10-13, and 16-21 drawn to an isolated polypeptide, and a composition thereof, classified in class 530, subclass 351.
 - III. Claims 14-21, drawn to an antibody to the polypeptide, a composition thereof, and an article comprising same, classified in class 530, subclass 387.9.
 - IV. Claims 16-21, drawn to a composition of an agonist of the polypeptide, and an article comprising same, classification depending upon the chemical entity of the agonist.
 - V. Claims 16-21, drawn to a composition of an antagonist of the polypeptide, and an article comprising same, classification depending upon the chemical entity of the antagonist.
 - VI. Claims 22 and 23, drawn to a method of treatment using the polypeptide, classified in class 424, subclass 85.2.
 - VII. Claims 22 and 23, drawn to a method of treatment using an agonist of the polypeptide, classification depending upon the chemical entity of the antagonist.
 - VIII. Claims 22 and 23, drawn to a method of treatment using an antagonist of the polypeptide, classification depending upon the chemical entity of the antagonist.
 - IX. Claims 22 and 23, drawn to a method of treatment using an antibody to the polypeptide, classified in class 424, subclass 139.1.
 - X. Claim 24 and 26, drawn to a method for determining the presence of a polypeptide using an antibody, classified in class 435, subclass 7.1.
 - XI. Claim 25, drawn to a method of diagnosis by detecting the expression level of a gene, classification depending upon the method steps.

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- XII. Claim 27, drawn to a method of identifying a compound inhibiting the *activity* of the polypeptide, classified in class 435, subclass 7.1.
- XIII. Claims 28 and 29, drawn to a method of identifying a compound inhibiting the *expression* of a gene encoding the polypeptide, classification depending upon the method steps.
- XIV. Claim 30, drawn to a method of identifying a compound mimicking the activity of a polypeptide, classification depending upon the method steps.
- XV. Claim 31, drawn to a method of stimulating the proliferation of T cells with a polypeptide or an agonist thereof, classified in class 435, subclass 7.1.
- XVI. Claim 32, drawn to a method of inhibiting the proliferation of T cells with an antagonist of the polypeptide, classification depending upon the chemical entity of the agonist.
- XVII. Claims 33 and 35, drawn to a method of decreasing the inflammatory cells in a mammal using a polypeptide or an agonist thereof, classified in class 424, subclass 85.2.
- XVIII. Claims 34 and 35, drawn to a method of decreasing the inflammatory cells in a mammal using an antagonist of the polypeptide, classification depending upon the chemical entity of the antagonist.
- XIX. Claim 36, drawn to a method for inhibiting angiogenesis in a mammal with an antibody to the polypeptide, classified in class 424, subclass 139.1.
- XX. Claim 37, drawn to a method for stimulating angiogenesis in a mammal with a polypeptide or an agonist thereof, classified in class 424, subclass 85.2.
- XXI. Claim 38, drawn to a method for inhibiting angiogenesis in a mammal with an antagonist of the polypeptide, classification depending upon the chemical entity of the antagonist.
- XXII. Claims 39 and 40, drawn to a method of treating a degenerative cartilaginous disorder in a mammal using a polypeptide, or an agonist thereof, and a kit comprising same for the treatment, classified in class 424, subclass 85.2.
- XXIII. Claims 39 and 40, drawn to a method of treating a degenerative cartilaginous disorder in a mammal using an antagonist of the polypeptide, and a kit comprising

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same for the treatment, classification depending upon the chemical entity of the antagonist.

XXIV. Claims 41-48, drawn to a method of detecting a polypeptide with another polypeptide, classified in class 436, subclass 501.

XXV. Claims 49-54, drawn to a method of linking a bioactive molecule to a cell expressing the polypeptide, classified in class 435, subclass 7.21

XXVI. Claims 55-58, drawn to a method of modulating a biological activity of a cell expressing the polypeptide with a polypeptide, classified in class 436, subclass 503.

XXVII. Claims 55-58, drawn to a method of modulating a biological activity of a cell expressing the polypeptide with an antibody, classified in class 435, subclass 7.1.

XXVIII. Claims 59 and 60, drawn to a method for detecting the presence of tumor in a mammal, classification depending upon the method steps.

The inventions are distinct, each from the other because:

The nucleic acid of Invention I is related to the polypeptide of Invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecules and proteins are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The method of Invention I is related to the polypeptide of Invention II as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the product as claimed may be isolated from their natural source or made by chemical peptide synthesis.

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The nucleic acid of Invention I is distinct from and unrelated to the antibody, the agonist, and the antagonist of the polypeptide in Inventions III, IV, and V, respectively, because they are physically and functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other. The method of Invention I is distinct from and unrelated to the products of Inventions III-V because the products may be neither made by nor used in the method.

Invention I is distinct from and unrelated to Inventions VII-XXVIII, wherein the nucleic acid of Invention I is neither made by nor used in the methods of Inventions VII-XXVIII, and wherein each does not require the other.

The polypeptide of Invention II is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

The polypeptide of Invention II is distinct from and unrelated to the agonist, and the antagonist of Inventions IV, and V, respectively, because they are physically and/or functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other.

The polypeptide of Invention II is related to the methods of Inventions VI, XII, XV, XVII, XX, XXII, XXIV-XXVI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for generating the antibody of Invention III.

Invention II is distinct from and unrelated to Inventions VII-XI, XIII, XIV, XVI, XVIII, XIX, XXI, XXIII, XXVII, and XXVIII, wherein the polypeptide of Invention II can be neither

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made by nor used in the methods of Inventions VII-XI, XIII, XIV, XVI, XVIII, XIX, XXI, XXIII, XXVII, and XXVIII, and wherein each does not require the other.

The antibody of Invention III is distinct from and unrelated to the agonist, and the antagonist of Inventions IV, and V, respectively, because they are physically and/or functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other.

The antibody of Invention III is related to the methods of Inventions IX, X, XIX, and XXVII, as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the purification of the polypeptide of Invention II.

Invention III is distinct from and unrelated to Inventions VI-VIII, XI-XVIII, XX-XXVI, and XXVIII, wherein the antibody of Invention III can be neither made by nor used in the methods of Inventions VI-VIII, XI-XVIII, XX-XXVI, and XXVIII, and wherein each does not require the other.

The agonist of Invention IV is distinct from and unrelated to the antagonist of Invention V, because they are physically and functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other.

The agonist of Invention IV is related to the methods of Inventions VII, XV, XVII, XX, XXII, as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for identifying a receptor for the polypeptide of Invention II.

Invention IV is distinct from and unrelated to Inventions VI, VIII-XIV, XVI, XVIII, XIX, XXI, XXIII, XXIV-XXVIII, wherein the agonist of Invention IV can be neither made by nor used in the methods of Inventions VI, VIII-XIV, XVI, XVIII, XIX, XXI, XXIII, XXIV-XXVIII, and wherein each does not require the other.

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The antagonist of Invention V is related to the methods of Inventions VIII, XVI, XVIII, XXI, XXIII, as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for identifying a receptor for the polypeptide of Invention II.

Invention V is distinct from and unrelated to Inventions VI, VII, IX-XV, XVII, XIX, XX, XXII, XXIV-XXVIII, wherein the antagonist of Invention V can be neither made by nor used in the methods of Inventions VI, VII, IX-XV, XVII, XIX, XX, XXII, XXIV-XXVIII, and wherein each does not require the other.

Inventions VI-XXVIII are drawn to independent methods, wherein each of the methods has different process steps, different active agents, different starting and ending points, and is for a different purpose, such that they require separate searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

2. Furthermore, regardless of which Invention applicants elect above, further restriction is required under 35 U.S.C. 121:

- A. One specific amino acid sequence (or a "PRO" number) with SEQ ID NO:, i.e. SEQ ID NO:2, 4, 6, 8, 10, 12, 14, 16, or 18, and
- B. The corresponding nucleotide sequence of "A" with SEQ ID NO:, i.e. SEQ ID NO:1, 3, 5, 7, 9, 11, 13, 15, or 17, and/or
- C. The corresponding cDNA sequence of "A" with ATCC accession number.

Applicants are required to make a further election from A, B, and/or C depending upon what type of sequences recited in the claims of the invention elected from groups I - XXVIII above. For example, if Group I invention (claims 1-9) is elected, further election from all three groups of A, B, and C would be required, as claim 1 recites polypeptide sequences listed in Group A; claims 2 and 3 recites nucleotide sequences listed in Group B; and claim 4 recites cDNA sequences listed in Group C.

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The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs or ATCC accession number represents a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In order to be fully responsive, Applicant must elect one from Groups I - XXVIII, one from Group A, and/or one from Group B, and/or one from Group C, even though the requirement is traversed. Applicant is advised that neither I - XXVIII nor A-B are species election requirements; rather, each of I - XXVIII, and A-C is a restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in dark ink and is positioned above the printed name and title.

**LORRAINE SPECTOR
PRIMARY EXAMINER**

DJ
1/14/03